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# Mediation designs for tobacco prevention research

David P. MacKinnon *, Marcia P. Taborga, Antonio A. Morgan-Lopez

*Department of Psychology, Arizona State University, Tempe, AZ 85287-1104, USA*

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**Abstract**

This paper describes research designs and statistical analyses to investigate how tobacco prevention programs achieve their effects on tobacco use. A theoretical approach to program development and evaluation useful for any prevention program guides the analysis. The theoretical approach focuses on action theory for how the program affects mediating variables and on conceptual theory for how mediating variables are related to tobacco use. Information on the mediating mechanisms by which tobacco prevention programs achieve effects is useful for the development of efficient programs and provides a test of the theoretical basis of prevention efforts. Examples of these potential mediating mechanisms are described including mediated effects through attitudes, social norms, beliefs about positive consequences, and accessibility to tobacco. Prior research provides evidence that changes in social norms are a critical mediating mechanism for successful tobacco prevention. Analysis of mediating variables in single group designs with multiple mediators are described as well as multiple group randomized designs which are the most likely to accurately uncover important mediating mechanisms. More complicated dismantling and constructive designs are described and illustrated based on current findings from tobacco research. Mediation analysis for categorical outcomes and more complicated statistical methods are outlined. © 2002 Published by Elsevier Science Ireland Ltd.

*Keywords:* Tobacco; Adolescents; Mediation; Indirect effects; Prevention; Methodology

## 1. Introduction

Although cigarette smoking is a major preventable cause of death and disease in the United States, about one-fourth of adolescents still smoke (Johnston et al., 1997). Young people are a primary focus of tobacco prevention activities because the majority of addicted smokers report starting smoking during adolescence and, once addicted to smoking, quitting is difficult. Some of these prevention activities include school-based programs, methods to control the availability of tobacco, and taxation (U.S. Department of Health and Human Services (USDHHS, 1994)). As summarized in the National Cancer Institute priorities for tobacco research beyond the year 2000,

> "While school-based approaches teaching skills to resist social influences to smoke have had some success in preventing tobacco use among youth, major gaps remain in our understanding of the most critical elements of tobacco prevention interventions..." (Tobacco Research Implementation Group, 1998, p. 18).

The purpose of this paper is to describe research methods and data analyses to identify the critical elements of tobacco prevention activities. A statistical method, called mediation analysis, tests whether programs change the variables they are designed to change, tests theory regarding tobacco use onset and cessation, and provides practical information on how programs can be improved (Judd and Kenny, 1981; MacKinnon, 1994). Mediation analysis may also help reconcile inconsistent results across tobacco prevention research studies (Hansen, 1992; Peterson et al., 2000; Tobler, 1986, 1997). A theoretical framework for program design, based on theory, is used to identify mediators in advance of program implementation (Chen, 1990). Tobacco program mediators and the components of the programs that targeted those specific mediators are discussed. Methods to investigate mediation are de-

* Corresponding author. Tel.: +1-480-727-6120; fax: +1-480-727-6176

*E-mail address:* david.mackinnon@asu.edu (D.P. MacKinnon).

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scribed, from existing approaches (Baron and Kenny, 1986; MacKinnon and Dwyer, 1993) to some new methods for analyzing mediation models in the special context of tobacco prevention.

The development of prevention programs based on theory has often been advocated (Flay, 1985, 1993; Lipsey and Pollard, 1989; Sussman 2001a; Weiss 1997). Lipsey (1993) calls for "small theory" to understand which components of a prevention program cause the effect on the outcome. From a careful review of theory in program evaluation Lipsey developed four recommendations, one of which is to:

> "Describe the mechanisms by which the planned treatment is supposed to have its effects. Specify any variables that are expected to mediate the effects of the treatment and the sequence of steps expected to occur between initial application of the treatment and the occurrence of its effects" (Lipsey, 1993, p. 34).

Several researchers argue for the identification and testing of theoretical mediating mechanisms that form the link between the program components and outcomes (Flay, 1985; MacKinnon, 1994; MacKinnon et al., 1991; McCaul and Glasgow, 1985; Sussman, 2001b).

Chen (1990) concretized the theoretical approach by identifying two critical aspects in the design and implementation of prevention programs—conceptual theory and action theory. Conceptual theory identifies the theoretical mediators hypothesized to be causally related to the dependent variable of interest. The conceptual theory for a prevention program is based on a wide variety of information including developmental theory and observed empirical relationships between mediators and outcome variables. The conceptual theory provides the justification for targeting certain mediating variables that are hypothesized to be causally related to tobacco use. Once mediating variables are identified, a researcher considers how to modify those variables with a program. Action theory refers to this link between the prevention program components and the mediators that the program is designed to change. Here, the researcher identifies program components that could modify the variables identified as putative mediators. Action theory considers the program intensity required to change the mediator in question. In some circumstances, a mediator that is less strongly related to the outcome variable is a primary target of the prevention program because it can be more realistically changed by the prevention program. Action theory is not often considered in tobacco prevention programs but the extent to which a program can realistically change a mediating variable may be the most important part of program development.

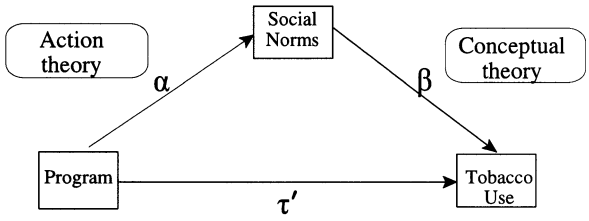


Fig. 1. One mediator model illustrating the incorporation of action theory and conceptual theory for tobacco use prevention. The mediator variable for this illustration is social norms.

Action theory and conceptual theory are illustrated in Fig. 1 for a one mediator model where a program targets the outcome variable through a mediator. Path α represents the action theory, the relationship between the prevention program and the mediator, social norms. Path β represents the conceptual theory for the relationship between social norms and tobacco use. One of the benefits of this framework is that, if program effects on tobacco use are not observed, it is possible to identify whether it was the action theory link or the conceptual theory link that failed. This type of analysis guides future research more than simply evaluating whether or not a program significantly changed tobacco use.

### 1.1. Conceptual theory

The conceptual theory that underlies a tobacco prevention program provides a basis for understanding the process which relates mediating variables to tobacco use (Botvin, 2000). The etiology of adolescent tobacco use is a complex process (USDHHS, 1994) that begins with cognitive factors including the formation of beliefs and attitudes favorable to use, and progresses through experimentation to regular smoking and then nicotine dependence (Flay, 1993). This process can take several years and has multiple interacting environmental, personal, and behavioral determinants, which vary for different stages of tobacco use (DiClemente et al., 1991; Mayhew et al., 2000). Studies that examine the etiology of tobacco use typically focus on identifying risk and protective factors that increase and decrease, respectively, the likelihood of tobacco use (Hawkins et al., 1992). For example, exposure to peers who smoke increases the likelihood of smoking while having parents who are nonsmokers decreases the likelihood of smoking (Chassin et al., 1998).

A non-exhaustive review of over 60 recent studies of tobacco use etiology reveals over 30 potential mediators of tobacco use. Most of these studies reviewed did not describe an explicit theoretical rationale as to why a mediator should be related to tobacco use. Table 1 illustrates several mediating variables and a brief theoretical rationale for how they change tobacco use.

Table 1
Conceptual theories linking youth tobacco use etiology to proposed mediators

| Tobacco use mediators | Conceptual theory |
|---|---|
| Refusal skills | Youth smoke because they do not have adequate skills to resist interpersonal and media pressures to smoke. |
| Social norms | Youth who perceive their immediate social environment as tolerant of smoking are more likely to smoke. |
| Perceived prevalence | Youth smoke because they believe "everybody does it." |
| Tobacco attitudes | Smoking is determined by a motivation to experience the benefits and avoid the consequences of smoking. |
| Knowledge of health consequences | Youth with a better understanding of the consequences of smoking are less likely to smoke. |
| Availability of tobacco | With less access to tobacco, youth will be less likely to smoke.<br>Youth who perceive the legal and/or economic sanctions for smoking as severe will be less likely to smoke. |

The key feature of the conceptual theory in program development is the consideration of underlying assumptions about how a particular mediator has an impact on tobacco use (Botvin, 2000). Studies that identify theory linking a mediator to tobacco use typically make reference to psycho-social, social-cognitive, or social-learning theories (Ajzen and Fishbein, 1980; Bandura, 1971; Jessor and Jessor, 1977). These larger theories provide frameworks for understanding how certain types of environmental cues (e.g. parents, peers, media) and cognition (e.g. social benefits, health consequences, perceived physiological effects) lead to increased risk for tobacco use. In short, these theories describe reasons that people begin and continue smoking.

### 1.2. Action theory

Once the conceptual theory is in place, the researcher has identified the mediating variables that need to be modified in order to reduce tobacco use. The next step in program design is selecting program components that will change those mediating variables (Langlois et al., 1999; see Lantz et al., 2000 for a review of tobacco prevention and control). This link from the prevention program to the mediators is the action theory link (see path $\alpha$ in Fig. 1).

Table 2 summarizes a non-exhaustive review of program components targeting the mediators identified in Table 1. It is clear from Table 2 that the same program components may target several mediators simultaneously even though they are often discussed separately in the conceptual theory stage. This non-orthogonality of mediators and components is an important characteristic for mediation designs to be discussed later in this article.

Table 2
Mediators of youth tobacco use which can be targeted through tobacco prevention program components

| Tobacco use mediators | Program component(s) targeting the mediator |
|---|---|
| Refusal Skills | Teach peer resistance skills<br>Teach decision making skills<br>Teach social skills<br>Teach verbal and non-verbal communication skills<br>Teach coping skills to deal specifically with the stress and anxiety that comes with saying no. |
| Social norms | Change social norms among friends<br>Implement school policy regarding smoking<br>Television advertising<br>Community based tobacco prevention messages (e.g. posters) |
| Perceived prevalence | Correct normative expectations regarding prevalence estimates of tobacco use |
| Tobacco attitudes | Provide information about the image of smokers as more negative than that of non-smokers<br>Disseminate information about long-term consequences<br>Disseminate information about short-term consequences<br>Disseminate information about the positive consequences of tobacco use |
| Knowledge of health consequences | Provide information about long-term effects of tobacco<br>Provide information about short-term effects of tobacco<br>Television advertising<br>Community based tobacco prevention messages (e.g. posters)<br>Warning labels on tobacco products |
| Availability of tobacco | Increase tobacco tax<br>Enforce laws restricting tobacco sales<br>Enforce laws for possession of tobacco<br>Indoor air laws/restrictions<br>Educate retailers<br>Facilitate retailer's ability to say no (e.g. signs in stores) |

The components could also be organized based on type of program components, rather than by level of intervention in Table 2. To use the categorizations adapted from Hansen (1992), the components in Table 2 can be broadly categorized into information components (e.g. correct prevalence estimates, disseminate information about the long and short term effects of smoking), social skills training (e.g. teach peer resistance skills, teach communication skills), intra-personal skills development (e.g. increase self-esteem, teach anxiety-coping skills, increase autonomy, increase awareness of outside influences), and availability components (e.g. indoor air laws, increase tobacco tax).

### 1.3. Examples linking action theory and conceptual theory

In this section, the theoretical rationale supporting the examination of the following six mediators of tobacco use is described: attitudes toward smoking, prevalence overestimation, perceived benefits of smoking, availability of tobacco, social norms, and refusal skills. These mediators were chosen because they have shown promise as effective targets for the prevention of tobacco use and the theoretical bases for all of these mediators provide examples of explicit statements about the underlying processes of how these mediators are related to tobacco use. These mediators are also among the easiest to link with program components.

Attitudes toward smoking predict both intent to smoke in the future and smoking onset (Chassin et al., 1981; Moreno et al., 1994). A theory that includes attitudes as a predictor of tobacco use is the theory of reasoned action (Ajzen and Fishbein, 1980). The theory proposes that one's attitude towards smoking, the perceived norms concerning smoking and the motivation to smoke, predict tobacco use. The underlying assumption about how attitudes affect smoking is that a person's beliefs about the benefits or consequences of smoking influences their attitude toward smoking, making their intention to smoke more or less likely. Program components to change attitudes include television media campaigns targeting the benefits and consequences of smoking (Goldman and Glantz, 1998).

Another potential mediator of smoking behavior is prevalence overestimation. Youth who overestimate the prevalence of cigarette use are at higher risk for tobacco use (Evans et al., 1995; Gerrard et al., 1996; Sherman et al., 1983). The underlying assumption is that youth smoke because they believe that a relatively high number of their peers smoke so that their own smoking allows them to fit in with their peers. If the overestimation of the prevalence rates were corrected through intervention, youth would be less likely to smoke because smoking would be seen as less normal, producing less pressure to fit in with the peer group by smoking. A program component that targets prevalence overestimation would present students with actual prevalence rates of tobacco use in their school.

Perceived positive benefits of smoking also predict smoking (Barton et al., 1982; Pechmann and Ratneshwar, 1994; Pierce et al., 1998). Investigations have distinguished between perceived health benefits and perceived social benefits. The assumptions are that youth smoke because they feel that smoking will alter their physical state in a positive way (e.g. weight reduction, reduction of social anxiety, regulation of negative affect) or that smoking will increase their popularity among their peer group because they will be more personally appealing (Barton et al., 1982; USDHHS, 1994). Program components to decrease perceived positive benefits include strategies to debunk the positive image of tobacco use in tobacco advertisements.

Easy access to tobacco products is a determinant of tobacco use by youth (USDHHS, 1994; Rigotti et al., 1997). Some tobacco prevention programs seek to reduce availability of tobacco products to youth by strengthening the existing policy or enacting stricter new policies regarding tobacco product sales to minors, accessibility to tobacco vending machines, and advertising of tobacco products (Ross et al., 1995). If young people have more difficulty obtaining tobacco, then they are less likely to smoke. Moreover, availability also contributes to the ambiguity between tobacco prevention activities in school-based prevention programs and the pro-smoking messages that youth observe and experience in their media (Lynch and Bonnie, 1994). One program component to change availability of tobacco is the use of vendor compliance checks to enforce laws forbidding tobacco sales to minors.

Resistance skills have received much attention in the literature on the etiology and prevention of tobacco use (Botvin et al., 1999; Hansen, 1992; Flay et al., 1994). Although investigators have found resistance skills to be related to tobacco use (Flay et al., 1994), others have found mixed results for resistance skills as a critical component of tobacco prevention program curricula (Botvin et al., 1989, 1999; Hansen, 1992). The assumption is that youth who are susceptible to tobacco use do not possess the skills to resist tobacco offers or are not confident in their abilities to resist both interpersonal and media influences to use tobacco. Role playing resistance skill training is one way programs target resistance skills.

Social norms exert a powerful influence on health behavior (Bandura, 1965, 1971). Peer influences, for example, are a strong predictor of smoking behavior, and most adolescent smoking is begun in the context of peer social interactions. Family norms also affect smoking. Adolescents who have family members who smoke or have family members who are accepting of smoking behavior are more likely to smoke (Chassin et al., 1998; Doherty and Allen, 1994). The media influences social norms regarding tobacco use such as in the portrayal of smoking in television and movies which then can gradually shape public opinion (Iyengar, 1991; McCombs and Shaw, 1972; Rogers and Dearing, 1988). If the social norm is less tolerant for tobacco use, presumably fewer persons will start using tobacco and current users will perceive increased social pressure to stop using tobacco. Correction of prevalence overestimation and discussion of attitudes regarding smoking typically confirm the established conservative social norm regarding smoking.

### 1.4. Prior research linking action theory and conceptual theory

The first study to use social influence theories to develop a tobacco prevention program was published 20 years ago by Evans et al. (1981). Evans et al. (1981) combined the existing theory of social–psychological communication (McGuire, 1969, 1974) with social-learning theory (Bandura 1965, 1971). At the time, tobacco prevention efforts focused on fear arousal. By contrast, the rationale of this study was that modeling desired behavior was an effective strategy for increasing that behavior. Based on this theory, they developed a video-taped prevention program for 7th graders to "inoculate" them against the social pressures to smoke by teaching them to identify peer pressure situations, coping strategies for those situations, and informing them of the negative health consequences of tobacco use. The tapes included information presented by peers in order to model the desired behaviors. Evans et al. did not measure the mediators (coping skills, peer pressure, knowledge of health consequences) but did report that participants were less likely to smoke 3 years after the program. Although they did not conduct mediation analysis, the theoretical approach guided the design by providing a framework under which to target mediators.

Two reviews of the literature on smoking prevention were published in 1985. Flay (1985) reviewed 27 school-based studies of smoking prevention and concluded that there was evidence that these approaches prevented smoking. The two most rigorous studies targeted media, information on immediate consequences, correction of misperceptions about smoking prevalence, discussion of family and media influences on smoking, role playing and learning of resistance skills, and public commitment. McCaul and Glasgow (1985) review the evidence for five major mediators of tobacco prevention programs, knowledge, attitudes, subjective norms, social competence, and intentions. The conclusion from both reviews was that researchers fail to consider how and why prevention programs work and that more studies need to measure and report program effects on mediators.

In part because of the articles advocating attention to mediation, Hansen and Graham (1991) conducted an experimental study of mediational processes in drug prevention. They noted that, at the time of their study, researchers were including several components in drug prevention programs, "defying precise theoretical interpretation." They noted that most of the successful programs included some peer pressure influence but that, often, it was the resistance skills component that was given credit for the success of the program. In order to understand what mediators might be more important, they designed four different programs to target those mediators and randomized students to one of the four programs. The first program provided information only (e.g. social and health consequences of tobacco use). The second added resistance skills training to the information component. The third added normative education (e.g. correcting prevalence estimates) to the information component. The fourth program combined information, resistance training, and normative education. The results indicated that the students in the normative education group had the lowest rates of tobacco use. There were no main effects for resistance skills (Donaldson et al., 1994; Hansen and Graham, 1991). The researchers did not conduct mediation analysis, but rather randomized students to conditions which they assumed would change mediators.

MacKinnon and colleagues (1991) used mediation analysis to examine the mediating mechanisms of the Midwestern Prevention Project (MPP). The MPP used a social influence theoretical framework in their program design with components including normative expectations regarding drug use and prevalence, recognition and counteraction of adult, media, and peer influences on drug use, peer and environmental resistance, assertiveness, problem solving for difficult situations, and a public commitment to avoid drug use. In addition, the program included a media campaign, a parent component, a community organization component, and policy programming to change perceptions about tolerance and prevalence of drug use. After 1 year, mediation analysis of the 42 schools participating in the MPP revealed that changes in perceptions of friends' tolerance of drug use was the most substantial mediator of program effects on tobacco use. The mediation analysis suggested that the program decreased perceptions of friends' tolerance which then decreased tobacco use. Resistance skills and beliefs about negative consequences were not significantly changed by the programs so they were not significant mediating mechanisms of the program.

Botvin et al. (1994, 1999) point out that, while the drug prevention research has found psychosocial approaches to be more effective than didactic approaches in preventing drug use, the work has not been fully extended to minority youth. They illustrate the feasibility of applying generic skills training techniques to reduce drug use intentions in Latino and African American samples. In 1999, Botvin et al. used a more comprehensive approach to target tobacco prevention in urban minority girls. Rather than focus only on generic life skills, as they did in 1994, the program was expanded to target social influence mediators. The program components included cognitive behavioral skills to enhance assertiveness, resist advertising, manage anxiety, communicate effectively, develop strong interpersonal relationships, and increase problem-specific skills. The mediators targeted by these components were: intentions to use, peer smoking norms, adult smoking

norms, risk taking behavior, attitudes towards smoking, smoking knowledge, refusal skills, and social acceptance. The authors found that 1 year after the program, the girls participating in the program were less likely to initiate smoking. In addition, they found the program had significant effects on intentions to use, peer smoking norms, adult smoking norms, risk taking behavior, knowledge of smoking consequences, and refusal skills. Each of those mediators also significantly reduced smoking initiation. There was evidence that decreasing risk taking and intentions to smoke, correcting perceived norms regarding adult and peer cigarette smoking, and increasing refusal skills and knowledge of smoking consequences mediated program effects.

Overall, the findings from the few studies that have addressed mediating mechanisms suggest that passive social influences, such as beliefs about peers, are a primary pathway to preventing tobacco use. Meta-analysis studies of substance use programs also suggest that social norms and programs that focus on peers are most effective (Bruvold, 1986; Tobler, 1986). Interestingly, a more recent study focusing on social influence (e.g. teaching resistance skills and increasing knowledge more than changing perceived norms/prevalence rates) did not have positive effects on smoking (Peterson et al., 2000) despite a good design and adequate implementation (Clayton et al., 2000). No mediation analysis has yet been conducted for this study, however. The few studies that have examined mediational processes find that resistance skills, knowledge alone, and beliefs about negative consequences do not mediate program effects on tobacco use (Botvin et al., 1994; Donaldson et al., 1994; Hansen et al., 1988; MacKinnon et al., 1991). The lack of attention to mediational processes is a significant limitation of tobacco prevention research. Mediation analysis in prevention studies is important because the processes that lead to behavior change are studied (MacKinnon, 1994). If the critical mediating processes are identified, then prevention programs can be improved by focusing on the most effective components and removing ineffective or even counterproductive program components.

## 2. Mediation analysis

Mediation analysis is a set of statistical analyses to investigate how a program worked or failed to work. There are two major aspects of mediation analysis as will be shown below. First, program effects on the mediators are examined in order to evaluate the action theory of the program. This step tests whether the program changed the mediators targeted by the program. Second, a test of the mediated effect itself is conducted, providing a simultaneous test of the effectiveness of the action theory and the conceptual theory of the prevention program. The test (actually a series of four steps to be described below) also provides information on the conceptual theory of the program by testing whether the mediator is significantly related to tobacco use.

### 2.1. One mediator model

In mediation analysis, the relationship between an independent variable and a dependent variable is decomposed into two effects, as shown in Fig. 1 for the single mediator model (Alwin and Hauser, 1975). One of these paths links the independent variable to the dependent variable directly (the direct effect), and the other links the independent variable to the dependent variable through a mediator (the indirect effect). An indirect, or mediated, effect implies that the independent variable causes the mediator (action theory), which, in turn causes the dependent variable (conceptual theory) (Holland, 1988; Sobel, 1990).

With the most common method to identify mediated effects, three hypotheses are tested based on estimates from regression equations (Baron and Kenny, 1986; Judd and Kenny, 1981). The first test requires that there is a significant effect of the independent variable ($X$) on the dependent variable ($Y$) as shown in Eq. (1).

$$Y = \tau X + \varepsilon_1 \tag{1}$$

where $Y$ is the outcome variable, $X$ is the program or independent variable, $\tau$ codes the regression coefficient between the program and the dependent variable which is the total effect, and $\varepsilon_1$ codes unexplained variability; the intercept is not shown to simplify the presentation. The logic here is that, in order for a program effect to be mediated, it is first necessary to show that there is a program effect. However, as described elsewhere (MacKinnon, 2000), mediation can occur even when there is not a significant relationship between the independent and dependent variable. In this case, there may be mediational processes that cancel each other out. For example, resistance training could increase the perception that people are using tobacco, while a normative manipulation decreases the perception that people are using tobacco. As a result, there may still be significant mediation in a tobacco prevention project even if the overall program effect is not statistically significant.

The second test requires that there is a significant program effect on the mediating variable, $X_M$, as summarized in the following equation where the regression coefficient relating the program to the mediating variable is $\alpha$, $X$ is the program or independent variable, and $\varepsilon_2$ codes unexplained variability. The intercepts are not shown in any of the equations to simplify presentation.

$$X_M = \alpha X + \varepsilon_2 \quad (2)$$

The third test requires that the mediator is a significant predictor of the dependent variable when both the independent variable and the mediator simultaneously predict the dependent variable.

$$Y = \tau' X + \beta X_M + \varepsilon_3 \quad (3)$$

In this equation, $\tau'$ is the regression coefficient relating the independent variable to the dependent variable adjusted for the effects of the mediator, $\beta$ is the regression coefficient relating the mediator to the dependent variable adjusted for the independent variable, and $\varepsilon_3$ codes unexplained variability. Note that the test of the $\beta$ coefficient is a test of the conceptual theory of the program. Fig. 1 displays the model defined in Eqs. (2) and (3).

MacKinnon (1994) adds a fourth step which is a test of the mediated effect. This fourth step can also be used as a single test for the mediated effect rather than testing the three hypotheses described above. The mediated effect, the product of the two parameters, $\alpha\beta$, is equivalent to the difference in the regression coefficients unadjusted and adjusted for the mediator, $\tau - \tau'$ (MacKinnon et al., 1995). There are a number of different analytical solutions for estimating the variance of the mediated effect $\alpha\beta$ or $\tau - \tau'$ (MacKinnon and Tein, 2002). Simulation work has shown that the variance estimates produced by the various methods are quite similar to each other and to the true value of the variance in situations involving continuous multivariate normal data and a continuous or binary independent variable (MacKinnon et al., 1995, 2002). The simplest of these variance estimates, accurate for both continuous and binary independent variables, is the first order Taylor series or the multivariate delta method solution (Sobel, 1982, 1986):

$$\sigma^2_{\alpha\beta} = \sigma^2_\alpha \beta^2 + \sigma^2_\beta \alpha^2 \quad (4)$$

The square root of this quantity provides an estimate of the standard error of the mediating variable effect. This standard error estimate can then be used to compute confidence limits which provide a general method to examine sampling variability of the mediated variable effect. If the confidence interval includes zero, there is evidence that the mediated effect is not larger than expected by chance.

### 2.2. Multiple mediator model

Because tobacco and drug prevention programs typically target several mediators, the multiple mediator model is the correct model for the evaluation of such programs as shown in Tables 1 and 2. Fig. 2 depicts a six mediator model with one independent variable. Conceptually, this model would work in much the same way as the one mediator model. That is, the experimenters identify multiple mediators from theory and research and then target all of those mediators with their program. This approach assumes that the same model works equally well for all individuals.

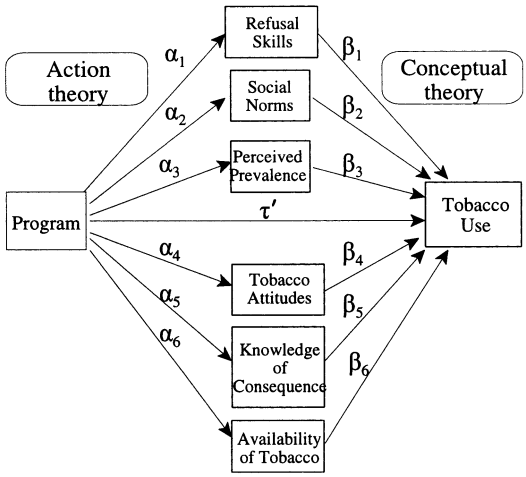


Fig. 2. One independent variable, six-mediator model illustrating the incorporation of action theory and conceptual theory for tobacco use prevention.

Typically, researchers apply the same model to all subjects operating under the assumption that all mediators relate to the outcome and that all subjects can benefit from being exposed to program components for all mediators. Regardless of the conceptual approach taken, a detailed statistical examination of the contributions of multiple mediators to changes in drug use may clarify the critical mediators for successful drug prevention programming as well as help resolve the discrepancies among studies.

The statistical methods for multiple mediators is a straightforward extension of the single mediator case. The regression equations for a six mediator model depicted in Fig. 2 are described below. The first equation is the same as in the single mediator case, where the total effect of the independent variable on the dependent variable is estimated.

$$Y = \tau X + \varepsilon_1 \quad (5)$$

where $Y$ is the dependent variable, $X$ is the independent variable, $\tau$ is total effect of the independent variable on the outcome variable, and $\varepsilon_1$ is the unexplained variability in $Y$ when it is regressed on $X$. Again, the intercepts are not shown in the equations to simplify presentation. An estimate of the effect of the independent variable on each mediator can be obtained by estimating the following regression equations.

$$X_{M1} = \alpha_1 X + \varepsilon_2 \quad (6)$$

$$X_{M2} = \alpha_2 X + \varepsilon_3 \quad (7)$$

$$X_{M3} = \alpha_3 X + \varepsilon_4 \quad (8)$$

$$X_{M4} = \alpha_4 X + \varepsilon_5 \quad (9)$$

$$X_{M5} = \alpha_5 X + \varepsilon_6 \quad (10)$$

$$X_{M6} = \alpha_6 X + \varepsilon_7 \quad (11)$$

where regression coefficients $\alpha_1$, $\alpha_2$, $\alpha_3$, $\alpha_4$, $\alpha_5$, and $\alpha_6$ code the program effects on each mediator and test the action theory for each mediator, $X_{M1}$ is the first mediator, $X_{M2}$ is the second mediator, $X_{M3}$ is the third mediator, $X_{M4}$ is the fourth mediator, $X_{M5}$ is the fifth mediator, $X_{M6}$ is the sixth mediator, and $\varepsilon_2$, $\varepsilon_3$, $\varepsilon_4$, $\varepsilon_5$, $\varepsilon_6$, and $\varepsilon_7$ code unexplained variability. The equation to test whether the mediators are significant predictors when both the independent variable and the mediators are included is shown in Eq. (12),

$$Y = \tau' X + \beta_1 X_{M1} + \beta_2 X_{M2} + \beta_3 X_{M3} + \beta_4 X_{M4} + \beta_5 X_{M5} + \beta_6 X_{M6} + \varepsilon_8 \quad (12)$$

where regression coefficients $\beta_1$, $\beta_2$, $\beta_3$, $\beta_4$, $\beta_5$, and $\beta_6$ are the adjusted effects of each of the six mediators and test the conceptual theory for each mediator, $\tau'$ is the regression coefficient relating the independent variable to the dependent variable adjusted for the effects of the six mediators, and $\varepsilon_8$ codes unexplained variability. The covariances among the mediating variables and the independent variable are included as part of the estimation of Eq. (12). The value of the total mediated or total indirect effect equals the difference in the independent variable coefficients $\tau - \tau'$, which is equal to the sum of six mediated effects $\alpha_1\beta_1$, $\alpha_2\beta_2$, $\alpha_3\beta_3$, $\alpha_4\beta_4$, $\alpha_5\beta_5$, and $\alpha_6\beta_6$. If a significant total effect ($\tau$) is reduced to zero (i.e. $\tau' = 0$) when the six mediators are included in the model, then the program effect is entirely mediated by the six mediators.

There are six specific mediated effects, $\alpha_1\beta_1$, $\alpha_2\beta_2$, $\alpha_3\beta_3$, $\alpha_4\beta_4$, $\alpha_5\beta_5$, and $\alpha_6\beta_6$, in addition to the total mediated effect which is the sum of all the mediated effects. The standard error of each mediated effect which can be calculated as shown in Eq. (13), with subscripts to identify the specific mediated effect tested as shown below for the $\alpha_1\beta_1$ specific mediated effect. Methods to test the equality of mediated effects are described in MacKinnon (2000).

$$\sigma^2_{\alpha_1\beta_1} = \sigma^2_{\alpha_1}\beta_1^2 + \sigma^2_{\beta_1}\alpha_1^2 \quad (13)$$

The multiple mediator models are based on two paths, the path from the independent variable to the mediator and the path from the mediator to tobacco use. It is likely that the relationships among the mediators form a more complicated chain, e.g. the program may change beliefs about tobacco use which then changes norms which then changes tobacco use. These mediated effects are then the product of the three regression coefficients in the multiple path model. It is interesting that the relationships among the mediators are not clearly related to action theory or conceptual theory, although both theories shed light on how these mediators are related. The specification of these more complicated relationships among mediators is most likely an area of future research after two-path mediation effects are investigated. Additionally, the relationships among mediators are correlational and as a result many different models may also adequately represent the data. More on the formulas for multiple path mediation is described in MacKinnon and Tein (2002).

Another mediator model discussed by Collins et al. (1998) allows for individual differences in a person-oriented approach to mediation. For example, subject A may need changes on all the mediators while subject B has accurate knowledge about prevalence rates and social norms, but has a high availability of tobacco and lacks refusal skills. The underlying model is the same for both subjects in that it is believed that all the mediators have a relationship with tobacco onset, but using the Collins et al. approach one would not give the same dose of each program component to these two subjects. Instead dose of the program would depend on the need for change on mediators. Therefore, the conceptual theory is the same for all subjects but action theory varies according to the subjects' needs. The approach that Collins et al. advocate may be more complicated in the planning stages, and not yet used. Such an approach may be ideal for prevention activities that are adapted to subjects such as computer-based prevention.

## 3. Mediator designs

### 3.1. Analysis for correlational studies with no program assignment

Cross-sectional, correlational studies examining the etiology of tobacco use can provide insight about the conceptual theory relating potential mediating variables to tobacco use. However, these types of studies have several obvious limitations for tobacco use prevention. In general, it is difficult to determine the direction of influence from cross-sectional studies (i.e. whether tobacco use changed the mediator or whether the mediator changed tobacco use). It is possible for tobacco use and cognitive mediators to have reciprocal influences such that each causes the other (Gerrard et al., 1996). In addition, covariation between the mediator and tobacco use may be due to another variable that is not measured but predicts both variables (Pedhazur, 1991). Correlational studies that examine etiology provide information only on the conceptual theory of the program.

### 3.2. Analysis of variation in program exposure but no control group

#### 3.2.1. Analysis of a single group design

This design is composed of an intervention where all participants receive a single program, with assessment of the mediator(s) and tobacco use at pre-intervention and post-intervention. The single group design allows for the assessment of change on the mediators and tobacco use after intervention. However, in the absence of a control group, it is difficult to establish how much, if any, of the change is due to the intervention. Several variables within the person and outside of the person could account for change across time (Campbell and Stanley, 1963) and, without a comparison group, none of these possibilities can be ruled out.

Measures of exposure to the program can be used to obtain information on mediating mechanisms (Weiss, 1997). It is important to keep in mind that approaches incorporating program exposure in mediation analysis can be very inaccurate in observational studies because exposure is not likely to be random. Two approaches are described here because they may increase the information obtained from a study and these designs can also be used in randomized studies. The mediation analyses would examine the variation in the exposure to the prevention program as the independent variable ($X$) in Eq. (5). In this situation, program exposure is like a measure of the dose of the program. Two hypothetical examples of program exposure analyses are described here. The first example is a school-based, ten-session tobacco prevention intervention in a single school whose students do not attend all the sessions so that variation in session attendance measures the dose of the program. In this situation, the independent variable is a continuous measure of the amount of program exposure. An analysis of covariance or a difference score analysis with program exposure as the independent variable in Eqs. (5)–(11) would be used to determine whether or not variation in exposure changed the mediators which then changed tobacco use. Here, instead of a prevention program effect for the $\tau$ (and $\tau'$ in Eq. (12)) parameter in Eq. (5), the $\tau$ (and $\tau'$ in Eq. (12)) parameter codes the implementation effect. Although this analysis may appear to eliminate some problems associated with the lack of a control group, the results are still very difficult to interpret clearly. A positive relationship between attendance (dose) and smoking (and mediators) may be caused by other factors such as conventionalism (e.g. Jessor and Jessor, 1977). Furthermore, when amount of program exposure is used to predict both the change in the mediator and the change in tobacco use, the direction of the relationship between the mediator and tobacco use remains difficult to determine.

A second example of a "dose response" study focuses on different implementation among schools rather than among individuals. Assume that there are nine schools in a study of a ten session program, where each school decides to use a different number of sessions (e.g. four schools use four sessions, two schools use five sessions, and three schools use all ten sessions). The same methods of analysis can be used as in the first case (although multilevel models may be more appropriate), but the interpretation of the analyses differs in that there is somewhat more confidence that the relationship between number of sessions and tobacco use would be unrelated to factors influencing individual self-selection. However, number of sessions in each school may be related to a school-level variable such as socioeconomic status (SES) which may also influence tobacco use directly and through the mediators. Because assignment to the number of sessions is not random, the attribution of effects to the program is difficult. Nevertheless, these studies may provide more information about mediational mechanisms than studies without any measure of program exposure.

#### 3.2.2. Analysis of multiple programs

Another design without a control group occurs when more than one prevention program is evaluated in a single study. For example, assume that three different prevention programs are delivered to three groups where, ideally, each program targets one or more different mediators. Here, examination of the mediated effect across groups is of primary interest as a way to test the theory underlying each of the three programs.

The independent variable in Eq. (5) is now more complicated because it is not continuous in the implementation case, but codes group membership. One option is to specify two independent variables to code group membership, with contrast codes comparing pairs of groups. In this case, there are separate action theory effects, $\alpha_1$ and $\alpha_2$, for each independent variable. However, this design would have the same difficulties in interpretation that are common to all designs where there is no control group to compare with the experimental groups. If there are no program effects, it may be that none of the programs worked or it could be that the programs had equivalent effects. However, mediated effects can be compared across groups and different hypothesized mediated effects across groups provide more compelling evidence for specific mediational processes.

### 3.3. Analysis of a program with a control group

#### 3.3.1. Analysis of a single program

The comparison of a prevention program to a control group is the most common type of tobacco prevention design. Adding a control group with which to compare the program group improves the validity of any study (Campbell and Stanley, 1963). The control group

provides a measure of the effect if the program group was left untreated (Dwyer et al., 1989; Robins and Greenland, 1992). As previously mentioned, ideally the program would be based on theory such that the program components target specific mediators so that each mediated effect can be tested.

An example of the program versus control group design is the MPP, based on social cognitive theory. The MPP (Pentz et al., 1989) targeted mediators like perceptions of friends' reactions to drug use and beliefs about the positive consequences of drug use. The program consisted of ten sessions to correct normative expectations and change beliefs. Forty-two middle schools were assigned to either control or treatment. Mediation analysis allowed the investigators to evaluate if any, all, or none of the mediator variables explained the program effect. Changes in perceptions of friends' tolerance mediated the program effects on tobacco use. Such analyses are important whether there was a program effect on tobacco use or not. If the program effect were explained by one or more of the mediators, there should be increases in mediators indicating that the program did in fact change the mediator (action theory) which would result in less tobacco use for the experimental group (conceptual theory). In this case, perceptions of friends' tolerance of tobacco use decreased (action theory), indicating that the program was effective at changing the mediator and the decrease in friends' tolerance decreased tobacco use (conceptual theory), supporting the social cognitive theory of the program.

When critical mediating processes are identified, then the prevention program can be improved by focusing on the most effective program components and removing ineffective or even counterproductive program components. If none of the mediated effects were significant, yet the program was effective at reducing tobacco use, this informs the researcher that some other, unmeasured mediational processes (e.g. attention that the experimental group received) may explain the effect. In any case, applying mediation analysis to the program can guide future research (MacKinnon, 1994).

#### 3.3.2. *Analysis of multiple programs*

An ideal study has several programs based on different theories of tobacco use and a control group. One program might target social norms, another program might focus on teaching resistance skills, and a third program might attempt to increase knowledge of the health consequences of tobacco use. A fourth group, a control group, would be included to control for secular changes in the outcome and mediator variables. Again, the independent variable would be changed to reflect contrasts among groups. One ideal strategy is to select contrast codes such that each group is compared to the control group. In this case of four groups, three contrast codes would be used in the mediation model.

A multiple program design can be informative, but one potential problem is that program components are often related and work together to change tobacco use, or have additive effects on tobacco use. For example, it is possible that none of the above-mentioned programs—the social norms program, the resistance skills program, or the knowledge of health consequences program—are able to reduce tobacco use independently, but when they were combined in one program, tobacco use decreases. Perhaps knowledge of health consequences helps the adolescent want to improve resistance skills and knowing the real social norms makes knowledge of health consequences easier to absorb. In order to better understand the processes by which programs have their effects, more complicated designs can be used. However, multiple program designs can be informative especially if there are theoretical reasons to believe that one program would be more effective, or work in a different way, than another program. Finally, this design can also be used to examine competing theories of tobacco use. In fact, mediation analyses in drug prevention research are most compelling when alternative theories predict different mediational pathways for program effects on drug use. For example, Hansen and Graham (1991) found evidence for the efficacy of the norm setting mediator but not the resistance skills mediator following experimental manipulation of these mediators. Similarly, social influence approaches have been more successful than affective based programs (Flay, 1985).

Although a control group improves the validity of the study, how units are assigned to groups is critical. For example, if adolescents self-selected into the experimental group and the control group was taken from the remaining population, covariates such as SES and baseline tobacco use may explain any changes in smoking. These and other non-equivalencies between the control and experimental groups can potentially bias the measure of tobacco use. Measuring any potential covariates prior to program implementation can reduce some of the bias that can occur as a result of non-randomized groups. The ideal situation is to randomize a large number of units to the experimental and control groups to minimize non-equivalence on any covariates.

### 3.4. *Examination of program components*

Once a program is found to be successful, it is reasonable to conduct further research to identify the most powerful components. Two designs are discussed here: dismantling and constructive research strategies (see also West and Aiken, 1997). With the dismantling strategy, the full program is compared to a version of the program where at least one component is removed.

In this strategy, the presumption is that the program component that is removed may not contribute any change in the desired outcome or may even produce change in the undesired direction. With the constructive research strategy, the full program or a reduced version of the program is compared to a version(s) of the program that has the additional component(s). In this case, the interest is in examining the increase in program efficacy of the added components (above and beyond the base program) as well as the normative rates of change. The same methods of analysis would hold for both strategies, with each strategy distinguishable only by which program is designated as the full program and the research question. Both strategies seek to answer questions about the incremental validity of individual program components (Kazdin, 1998). Such designs are useful in terms of cost-benefit analyses in order to make decisions about adding and deleting program components (West and Aiken, 1997). They also facilitate decisions about which program components would be included in a version of the program that is instituted by an agency after the intervention trial phase of the program (Sussman, 2001a).

Separate program components may each have an impact on only one mediating variable. In this case, program components are orthogonal. However, a single program component likely affects more than one mediator and a single mediator may be influenced by more than one program component. In both cases, program components are nonorthogonal. When single program components are intended to influence single mediators, but have unintended influences on other mediators (Kellam and Rebok, 1992), sequential random assignment to program components may increase understanding. For example, in the 1st week of a program, subjects are randomly assigned to receive the first component or not. During the 2nd week, subjects are randomly assigned to receive the second component and so on. The analysis of this design would be similar to the method described for the analysis of multiple program groups with a control group.

As it is possible for program components to be nonorthogonal, program mediators may be nonorthogonal as well. There are clear examples in the literature on the etiology and prevention of tobacco use for correlated mediators. For example, a tobacco prevention intervention that only targets tobacco refusal self-efficacy may also have an impact on norms regarding smoking (Flay et al., 1994). However, change in both of these mediators would be difficult to interpret in the single component framework. In this hypothetical example, change in perceived parental approval may be due to its correlation with social norms or program content that may affect both mediators. In this case, a constructive research strategy comparing a self-efficacy only component, a social norm plus a parental approval component and an equivalent no-treatment group might offer a solution for disentangling this problem of interpreting intervention effects with correlated mediators and correlated components.

### 3.5. Extensions of the mediation model

The above description of mediation analysis was for the case of all continuous and reliable measures, normal error terms, individual level of analysis, and one or two measurement occasions. The purpose of this section is to describe several extensions of the model to include categorical variables, multilevel data structures, and repeated longitudinal measurement. Computer programs to estimate the mediation model described in Section 2 along with software to conduct the analysis described below is available at the website, http://www.public.asu.edu/~davidpm/.

Although there are several measures of tobacco use that may approximate an interval scale such as the number of cigarettes smoked (and combinations of measures of lifetime, monthly, and weekly smoking), most measures of tobacco use are categorical. Tobacco use in the last month is an example of a typical measure of tobacco use among adolescents. In this case, ordinary regression analysis of a binary outcome violates several assumptions of ordinary regression analysis. Logistic or probit regression is the appropriate analysis for these data (Hosmer and Lemeshow, 2000). The procedure to estimate mediated effects and the standard error of mediated effects for categorical data differs somewhat from the methods described in Section 2, because the error variances are fixed as in Eqs. (1) and (3) in logistic or probit regression (Fienberg, 1980; MacKinnon and Dwyer, 1993; Winship and Mare, 1983). One solution for mediation analysis with categorical data is to standardize logistic and probit regression estimates and standard errors prior to conducting mediation analysis as described in MacKinnon and Dwyer (1993). Alternatively, a covariance structure analysis program such as MPLUS (Muthén and Muthén, 1998) can be used to conduct a similar analysis that explicitly models the categorical variables. Person-oriented approaches to assessing mediation (Collins et al., 1998) are especially relevant for studies with categorical measures of smoking and mediating variables.

In many prevention studies, particularly in school-based prevention activities, participants are clustered within larger groups. In this situation, the assumption of independent observations is violated and typical analyses can be misleading because type 1 error rates are increased (Barcikowski, 1981) which also occurs when examining mediation effects (Krull and MacKinnon, 1999). A measure of the violation of the independence of observations within a group is the intraclass correlation (Haggard, 1958; Murray et al., 1994) which is a measure

of the extent to which individuals in a particular group (e.g. school) are more like each other than they are like members of the other groups (e.g. other schools). In addition, in many prevention studies, it is the individual-level effects rather than group-level effects, that are of primary interest. Multilevel modeling techniques do not assume independence among observations and individual and school level effects can be examined. Multilevel mediation analysis is particularly suitable when a program is randomized at the group level and the mediator and outcome are measured at the individual level. Mediation analysis for multilevel models is described in Krull and MacKinnon (1999). Multilevel models are also useful for examining mediation effects at several levels including community, school, and individual. Multilevel analysis is ideal in situations where one mediator may operate through changes in overall school climate while a different mediator operates through individual cognitions. Substantive applications of multilevel mediation examining etiological processes are also beginning to appear (Raudenbush and Sampson, 1999).

Long term mediation effects are often of interest to tobacco prevention researchers. Although difference score and analysis of covariance methods provide an accurate assessment of program effects, more sensitive methods to examine change over time are available (Bryk and Raudenbush, 1992; Rogosa, 1988). One of these methods, longitudinal growth curve modeling, models individual growth rates over time as well as modeling the influence of interventions on mediators and outcomes (Raudenbush, 2001). Variants of these models have been used to examine the influences of program effects on non-linear growth (Muthén and Muthén, 2000) and methods designed especially for the evaluation of intervention trials have been introduced (Muthén and Curran, 1997). These growth curve models can also be applied to categorical outcomes using the MPLUS computer program.

Growth curve coefficient modeling methods have rarely incorporated mediational processes in the examination of longitudinal trajectories, although work is beginning to appear in this area. Cheong et al. (in press, 2001) demonstrate the use of parallel process and sequential process models in the examination of both direct and mediated effects on substance use. Both models assume that a program is designed to change individual growth trajectories on a mediator which, in turn, should lead to change in the growth trajectories of the outcome. Parallel process models examine the impact of the program on both the mediator and the outcome variable when the mediator and outcome are measured at the same time so that the relationship between the mediator and the outcome (controlling for the effects of the program on both) will be correlational (Cheong et al., 2001).

Sequential process mediational models allow for evaluation of the effects of an intervention on early growth on a mediator, which in turn influences growth on the outcome variable at a later timepoint. If the mediated effect demonstrates that the program influences early growth on the mediator, which in turn influences later growth on the outcome, there would be more confidence in the predicted causal sequence (e.g. program → mediator → outcome). For example, early improvements in resistance skills during elementary school may reduce growth in tobacco use in high school.

Moderator variables alter the strength of the relationship between two other variables (Aiken and West, 1991) and can also alter the strength of the relationships in a mediation model (Baron and Kenny, 1986; Donaldson, 2001). In the context of program evaluation, it is possible that the program did not have a consistent mediation effect across particular subgroups (e.g. age, gender, ethnicity, SES, program implementation) or across pre-intervention variables that affect mediators as well as tobacco use (e.g. risk and protective factors) (Morgan-Lopez et al., in press, Tein et al., 2000; Unger et al., 2000; Wolchik et al., 1993). Moderated mediation models examine whether the mediated effect of the program differed across subgroups (Botvin et al., 1989, 1992; Donaldson, 2001; James and Brett, 1984). An example of a mediated moderation effect is a mediated effect through social norms that depends on risk-taking propensity. Mediated moderation is investigated by identifying the mediators of the risk-taking by program exposure interaction. Examination of an interaction effect between the mediator and program exposure is also a moderator effect that is important for accurate interpretation of mediated effects. Moderator effects may also provide further evidence for mediational processes if mediated effects differ across subgroups that differ on the baseline measure of the mediating variable. Combining mediation and moderation analyses may aid in cost-benefit decisions in terms of which groups, pre-existing conditions or combinations of mediators need to be targeted by particular program components. In summary, the generalizability of the mediated effect is assessed when mediation and moderation are combined (Morgan-Lopez and MacKinnon, 2001).

## 4. Discussion

The purpose of this paper was to outline designs for mediation analysis in prevention studies. Mediation analysis is appropriate for any tobacco prevention or cessation study as long as measures of tobacco use and mediating variables are available. There are many reasons for conducting mediation analysis in tobacco prevention programs. First, the mediation model spe-

cifies tests for action theory for how the program changes mediators and also the conceptual theory for how the mediators are related to tobacco use. Second, the random assignment of subjects (to receive or not to receive a prevention program or to a particular level of a mediator within the prevention program) provides an ideal test of the theory of a prevention program. If a mediator is causally related to tobacco use then changing the mediator should lead to reduced tobacco use.

Designs for several different types of studies were outlined. Most studies can shed light on the mediational processes involved in tobacco prevention as long as measures of tobacco use and mediators are included in the study. The validity of the research conclusions depend on the mediation design used. In particular the randomization of units to conditions improves accurate interpretation of program effects. Even in this situation, however, the relationship between the mediator and the outcome variable can go in either direction, i.e. tobacco use causes the mediator or the mediator causes tobacco use. As a result, it is best to view mediation analysis as a tool in a program of research, moving from correlational studies informing action and conceptual theory to evaluation of a randomized prevention program. Results from these studies then inform additional studies of program components, comparison of alternative programs, and finally sequential assignment of program components.

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